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Registration Decision RD2011-04

Typhula phacorrhiza Strain 94671

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Registration Decision for *Typhula phacorrhiza* strain 94671

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Nivalis Technical and the end-use product Nivalis, containing the microbial pest control agent (MPCA) *Typhula phacorrhiza* strain 94671, to suppress both gray snow mould (*Typhula incarnata* and *Typhula ishikariensis*) and pink snow mould (*Microdochium nivale*) in turfgrass on golf courses.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2010-23, *Typhula phacorrhiza strain 94671*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Typhula phacorrhiza* strain 94671 and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2010-23. This decision is consistent with the proposed registration decision stated in PRD2010-23.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-23, *Typhula phacorrhiza strain 94671* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*" ...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is *Typhula phacorrhiza* strain 94671?

Typhula phacorrhiza strain 94671 is a fungus which belongs to the same genus as the gray snow mould pathogens (*Typhula ishikariensis* and *Typhula incarnata*) on turfgrass. As the active ingredient in Nivalis, *Typhula phacorrhiza* strain 94671 suppresses both gray snow mould (*Typhula incarnata* & *Typhula ishikariensis*) and pink snow mould (*Microdochium nivale*) in turfgrass. *Typhula phacorrhiza* strain 94671 competes directly with snow mould pathogens for nutrients and space under snow cover and suppresses disease development due to lack of food and space.

Health Considerations

Can Approved Uses of *Typhula phacorrhiza* strain 94671 Affect Human Health?

***Typhula phacorrhiza* strain 94671 is unlikely to affect your health when Nivalis is used according to the label directions.**

Exposure to *Typhula phacorrhiza* strain 94671 may occur during handling of Nivalis or when on a golf course with treated turf.

When assessing the health risks associated with microbial active ingredients, several key factors are considered: a microorganism's biological properties (for example, production of toxic byproducts); reports of any adverse incidents; potential to cause disease or toxicity as determined in toxicological studies; and the likely levels to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism. Toxicology studies in laboratory animals describe potential health effects from large doses for the purpose of identifying potential to cause disease or toxicity. There were no signs that *Typhula phacorrhiza* strain 94671 caused any significant toxicity or disease when tested on laboratory animals.

Residues in Water and Food

Dietary risks from food and water are not of concern as there are no food uses and the likelihood of residues of *Typhula phacorrhiza* strain 94671 contaminating drinking water supplies is negligible.

Occupational Risks From Handling Nivalis

Occupational risks are not of concern when Nivalis is used according to label directions which include protective measures.

Users of Nivalis can come into direct contact with *Typhula phacorrhiza* strain 94671 primarily via the inhalation of dusts or exposure to the skin. As a standard requirement intended to minimize exposure, the label specifies that users of Nivalis must wear a long-sleeved shirt, long pants, closed footwear, waterproof gloves and a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter for biological products. A warning to avoid breathing dusts and to avoid contact with eyes is also on the end-use product label.

For bystanders, exposure is expected to be much less than that of workers involved in loading and application activities and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Typhula phacorrhiza* strain 94671 Is Introduced Into the Environment?

Environmental risks are not of concern

Typhula species are commonly found on organic debris throughout temperate regions of the world and can cause diseases of cereals and grasses at low temperatures. Although some strains of *Typhula phacorrhiza* have been shown to be pathogenic to certain wheat cultivars, testing for pathogenicity on plants with the MPCA showed no adverse effects. The annual directed method of application of the end-use product prior to snowfall reduces exposure to non-target plants and organisms, therefore environmental risks are very low.

Value Considerations

What Is the Value of Nivalis?

Nivalis is a biofungicide that suppresses gray and pink snow mould on turfgrass

Nivalis contains dried mycelium and sclerotia of the fungus *Typhula phacorrhiza* in inoculated millet seeds. It has demonstrated effectiveness in suppressing both gray snow mould (*Typhula incarnata* & *Typhula ishikariensis*) and pink snow mould (*Microdochium nivale*) in turfgrass. Nivalis is to be used on turf where continuous snow cover persists for 90 days or more. It provides a much wider window of opportunity for application compared to the conventional fungicides since Nivalis can be applied well before the snow cover. Nivalis provides an additional mode of action to suppress snow mould on turf.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Nivalis to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

To minimize exposure to *Typhula phacorrhiza* strain 94671, all handlers, loaders and applicators of Nivalis must wear long-sleeved shirts, long pants, waterproof gloves, closed footwear, and dust/mist filtering respirators/masks (NIOSH approval number prefix TC-21) or NIOSH approved respirators with any N-95, R-95, P-95 or HE filter for biological products. A label statement directing users to avoid inhaling dusts and to avoid contact with eyes is also included.

Environment

As a general precaution, statements will be added to the label to prohibit handlers from contaminating aquatic habitats including lakes, streams, ponds or other waters.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2010-23, *Typhula phacorrhiza strain 94671)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra infoserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act*.